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Incubator and Analyzer For High Volume Throughput

Background of the Solution

Clinical analyzers using slide test elements as the test vehicle conventionally supply them from cartridges to a sample dispensing station and then to an incubator. Conventionally, the incubator provides a generally horizontal support surface whereon the test elements are positioned side-by-side, e.g., around the circumference of a rotor in a common plane.

Such an arrangement is suitable when the volume of test elements tested in an hour is not large, say for example 300 tests per hour. However, there has been a need in the market for analyzers that provide a much higher throughput, e.g. 1,200 tests per hour. If the same incubator were to be used for such an analyzer, the incubator would be a bottleneck for high throughput. E.g., only 24 tests elements can occupy the incubator of the "V250"™ analyzer at a time. Obviously, more or different incubators are needed for 1,200 tests per hour.

Summary of the Solution

There is provided an incubator support for moving slide test elements through an incubator in a closely-packed relationship, comprising:

a base plate;

and a plurality of supports spaced along the base plate, each support comprising a pair of surfaces, each pair defining a pair of intersecting planes that are stepped out of the planes of the paired surfaces of at least one adjacent support in a repeating cycle, each pair of surfaces forming an interior angle of generally 90° and being constructed so as to capture a first side edge and a bottom surface of a supported test element, one of each the paired surfaces being adapted to support the bottom surface and having a width less than the width of the supported bottom surface;

so that a test element supported by a pair of surfaces overlaps a test element of an adjacent pair of surfaces and the packing density of the slide test elements per lineal inch of incubator support, is increased.

There is also provided an incubator support for moving slide test elements through an incubator in a closely-packed relationship, comprising:

a base plate having a bottom face defining a general plane of motion of the support, and an upper face opposite to the bottom face; and a plurality of individual test element support surfaces spaced along the upper face, the surfaces being constructed to support at least a first and a second slide test element thereon adjacent to each other; each of the plural support surfaces being angled out of the bottom face plane of motion by an amount sufficient to allow one of the first and second slides on a support surface to overlap without contacting

the other of the first and second slide test elements disposed on an adjacent support surface, so that the packing density of the slide test elements per lineal inch of incubator support, is increased.

There is further provided an analyzer for conducting assays of patient sample liquids on slide test elements at a relatively high throughput, the analyzer comprising:

a source of slide test elements; a dispensing station for depositing a patient sample liquid on a slide test element;

an incubator removably holding a plurality of slide test elements deposited with the sample liquid, spaced around the circumference of the incubator on support surfaces each holding a test element partially overlapping another test element on at least one of the adjacent support surfaces; a pusher blade for moving a slide test element from the dispensing station to the incubator; and a ramp for guiding the pusher blade and a test element pushed by the blade, to move from the dispensing station to the incubator.

There is still further provided apparatus for protecting and positioning a slide test element within an incubator on a support, the apparatus comprising:

a cover for contacting a top surface of a test element on such support, the cover having two opposed side edges, one of the side edges including a lip dependent therefrom so that the cross-sectional shape of the cover is generally that of an "L", and a spring for biasing the cover in a predetermined direction to press the cover down and the lip towards a corresponding side edge of a test element covered by the cover; so that a covered slide test element is biased by the cover lip in the predetermined direction on the support.

Brief Description of the Drawings

Fig. 1 is a simplified block diagram of an analyzer utilizing the present solution; Fig. 2 is a fragmentary isometric view of a portion of an incubator constructed in accordance with the solution, the spring for one of the covers being shown in phantom; Fig. 3 is a fragmentary front elevational view of the incubator portion shown in Fig. 2, showing two covers and respective springs in solid lines, and an alternative embodiment based on the horizon shown in phantom; Fig. 4 is a fragmentary plan view of the incubator portion shown in Fig. 3; Fig. 5 is a fragmentary elevational view in section showing a representative analyzer construction cooperating with the incubator of the solution; Fig. 6 is a section view taken generally along the line VI-VI of Fig. 5; Fig. 7 is a fragmentary elevational view partly in section, showing an alternative embodiment of the solution; Fig. 8 is a fragmentary isometric view of another alternative embodiment of the solution, the cover being omitted for clarity; Fig. 9 is a section view taken generally along the plane of the line IX-IX of Fig. 8, with the cover added; Fig. 10 is a

fragmentary isometric view of the alternate embodiment of Fig. 3 shown in phantom; Fig. 11 is a fragmentary elevational section view taken generally through the line XI-XI of Fig. 10 along the axis of the plunger; and Fig. 12 is a fragmentary elevational view similar to that of Fig. 5, but showing yet another alternative embodiment useful with the embodiment of Figs. 10 & 11.

Description of the Preferred Embodiments

The solution is useful regardless of the kind of slide test elements used, regardless of the construction of other elements of the analyzer apart from the incubator, regardless of whether the incubator is a rotating rotor or is a linearly operated support, and regardless of whether detection is on the incubator or off of it.

In brief, the increased packing density feature of the solution, is achieved by constructing the support surfaces of the incubator so that, unlike prior art constructions, each of the test elements on the incubator support surfaces overlap at least one of the test elements adjacent to it. A variety of constructs is possible to achieve this.

First, a description of the environment of the solution:

The test elements stored on the incubator can be any generally flat slide formats. Useful analyzers 10 to incorporate the incubator 20 of this solution are those which, Fig. 1, provide slide test elements from a slide supply station 12, usually via a pusher blade symbolized by the arrow 14, to a sample dispensing station 16. (An example of this is described hereinafter.) From there the test element with its deposited sample is pushed, arrow 18, to incubator 20, here shown as a rotating incubator. Conveniently, the test elements are read, arrow 22, by a conventional detection or reader station 24, while still on the incubator.

In accordance with one aspect of the solution, incubator 20, Fig. 2, comprises a plurality of paired surfaces 30, 32, spaced apart on the top surface of a rotor base plate 34, each pair defining a pair of intersecting planes that are stepped out of, or mis-aligned with, the planes of the respective paired surfaces for at least one of the adjacent test elements E. The effect is to create a repeating cycle of saw-teeth, Figs. 2 and 3, around approximately the entire circumference 40 of rotor base plate 34 (rotated by a conventional drive, not shown). That is, each surface 30 of a pair intersects with the other surface 32 at an interior angle alpha, Fig. 3, which is preferably generally 90°. As used herein, "generally 90°" means that it need not be perfectly 90°, but it can vary therefrom ± about 1°. Base plate 34 has a bottom surface 41 which forms a generally flat base, Figs. 2 & 3, defining a rotor plane of reference.

20°, for a test element thickness of about 1.1 mm. Angle beta is also the angle of inclination of each support surface 30 out of the plane of rotation of plate 34, arrow 71.

As noted above, preferably each incubated test element is read or scanned while on the incubator. To this end, base plate 34 is apertured at 70 through to surface 30, Fig. 2, at a position that underlies the detectable portion of test elements E held supported thereon. Additionally, base plate 34 is grooved at 72, to allow a conventional picker mechanism to pull a read test element off the incubator for discarding.

By careful machining of surfaces 30 so as to all be at the same height Z at the aperture 70, Fig. 3, from the bottom of base plate 34, it is possible to eliminate significant errors in detection due to so-called Z-axis variation effects on the reading of the test elements.

To arrange for test elements E to be turned out of the horizontal by angle beta upon contact with a cover 50, a suitable mechanism is provided, Fig. 5. That is, conventionally in an analyzer 10 a test element is dispensed from slide supply station 12 in a horizontal orientation, which is per force different from the test element's orientation on each support surface 30 of this solution. Fig. 5 thus illustrates both a conventional slide supply station 12, and the suitable mechanism for re-orienting the test element for incubation.

Thus, as is more particularly described in U.S. Patent No. 5,089,418, the details of which are expressly incorporated herein by reference, station 12 can comprise concentric rings 122,124 of cartridges C containing test elements E and E'. The cartridges are releasably held by nesting members 132, and plungers 134 are used to raise a cartridge up against a floating member 140 for each ring 132, biased by spring 148 downwardly to provide a clear path through opening 150 for a pusher blade 141 to pass over that ring. However, plunger 134 is effective to override spring 148 so that passageway 157 at the top of the cartridge, aligns with openings 160,164,168 of the analyzer through which blade 141 passes.

As a result, a test element E or E' is ejected from a cartridge from either ring, to the dispensing station 16 where a disposable tip 170 is used to deposit a patient sample liquid, arrow 172, onto the ejected test element supported horizontally by surface 174.

From station 16, a ramp 180 is used to re-orient the test element to angle beta, Fig. 6. The ramp preferably comprises a fixed, stationary tunnel 182 that twists from a horizontal orientation at position 184, Figs. 5 and 6, to the tilted orientation of angle beta at position 186. The height "h" of the opening through the tunnel 182, Fig. 5, is slightly greater than the thickness of the test element. Because pusher blade 141 is

Surface 30 of the paired surfaces 30,32 acts as the support for the bottom surface 36 of a test element E, Fig. 3. Surface 32, on the other hand, is a reference datum surface for one side edge 38 of a test element.

It will be readily apparent, Fig. 3, that the width of surface 30 is less than the width W of a supported test element, by exactly the distance X comprising the amount of overlap of the next adjacent test element.

To bias side edge 38 against datum surface 32, a cover 40 is provided, Figs. 2-4, biased by spring 50. (The spring is shown in phantom, Fig. 2.) Cover 40 preferably comprises a flat plate 42 and a lip 44 depending from one edge thereof, Figs. 2-3, creating an L-shape when seen end-on, Fig. 3. End 46 of cover 40 illustrates a preferred camming chamfer 48 formed on the inside of lip 44.

Cover 40 has a side edge 49 opposite to lip 44, which falls short of contact with datum surface 32, leaving a gap "G", Fig. 3, but only when a test element E is covered by cover 40.

To bias cover 40 downwardly, arrow 52, and to the left, arrow 54, Fig. 3, spring 50 is provided, preferably as a leaf spring although a wire spring can also be used. As more clearly shown in Fig. 4, spring 50 has an inner end 56 pinned at 58 to plate 34, and an outer end 60 pinned at 62 to cover 40. A body portion connects the two ends, and this portion is necked down at 64 to allow for spring 50 to twist sideways slightly against its bias 54 during test element loading.

Thus, in the absence of a test element on a given support surface 30, the cover 50 for that support surface presses down and to the left so that its side edge 49 contacts datum surface 32, Fig. 3, and the under surface 66 of cover 50 contacts support surface 30. However, when a test element E is pushed, arrow 68, Fig. 4, into contact with cover 50, the latter is cammed up and to the right, by reason of camming chamfer 48, Fig. 3. A similar camming chamfer, not shown, is preferably provided on bottom 66. Side edge 69 of slide E is thus pushed to the left by its contact with lip 44.

The result is that test elements when loaded onto the incubator, each overlap at least one adjacent test element by the linear distance "X", but without contact with each other. This amount of overlap will vary, depending upon the increased packing density required, per lineal inch of incubator support. For example, a highly useful amount is where X = about 18% of the total width W of the test element.

To allow each test element to be loaded onto plate 34 at substantially the same place in the analyzer, that is, the same tilt out of the horizontal and at the same height, preferably each surface 30 is angled at substantially the same angle beta out of the horizontal. Again, beta can vary, especially depending on the thickness of the test elements E, but it is preferably between about 15° and about 25°, for example, about

flexible, as described in the aforesaid '418 patent, it will twist sufficiently to allow traversal of a tunnel 182 as the test element is pushed onto incubator surface 30.

(The section of tunnel 182 as shown in Fig. 5 is taken approximately along the line V-V of Fig. 6.)

The covers for each test element are described above as being individual components that move up and down against a spring above the cover, depending on whether a test element is pushed under the cover, or withdrawn from under the cover. However, it is not essential that the covers be constructed in this fashion. Instead, Fig. 7, a single overall stationary cover can be constructed for the entire rotor, and the spring can be simply a sideways-acting member that works only to push the side edge of a captured test element against the reference datum surface of the support of the rotor. Parts similar to those previously described bear the same reference numeral, to which the distinguishing suffix "A" is appended. (Fig. 7 is technically a view of a linearly extending incubator support, but it applies equally well to a rotor if the linear view is wrapped around a rotational axis to depict a circumference.) Thus, incubator 20A comprises a base plate 34A having on its top surface a saw-tooth pattern of paired surfaces 30A, 32A to capture a test element E inclined at an angle beta from the horizontal, all as described above. However, cover 40A is modified so as to be one single, integral piece. It has a saw-tooth surface 200 that is complimentary to surfaces 30A, 32A, comprising major surfaces 230 and minor surfaces 232 in pairs. Surfaces 230 are fixedly positioned above surfaces 30A by a distance "D_1", effective to snugly receive a test element E between cover 40A and surfaces 30A. More specifically, elements E need to be biased downwardly and covered at their open central area. Both of these functions can be accomplished by a leaf spring 233 on surfaces 230, which cover over the open area of elements E and bias the elements downwardly. An example of D_1 that allows for this is 1.2 mm for a thickness of 1.1 mm for elements E.

On the other hand, surfaces 232 are spaced from respective surfaces 32A by a distance "D_2", that is larger than D_1. That is, distance D2 must accommodate the overlap "X", as well as provide space for a leaf spring 240 that biases against edge 69A of test element E to push its opposite edge 49A against reference datum surface 32A.

Viewing apertures 70A are provided in plate 34A as in the previous embodiment.

The above embodiments all involve a saw-tooth support pattern that repeatedly extends up, down, up, down, one step at a time, to support test elements inclined all out of the plane of the horizontal. It is not essential, however, that the test elements be supported non-horizontally. They can be supported horizontally, and still overlap, as shown in Figs. 8 and 9.

Parts similar to those previously described bear the same reference numerals, to which the distinguishing suffix "B" is appended. Thus, incubator 20B comprises a rotor featuring a base plate 34B having spaced along it circumference at its top surface, a plurality of paired surfaces 30B, 32B, each pair creating interior angles alpha that serve to capture a test element E for incubation all as described above. Also as described above, the width of support surface 30B is less than the width W of the supported test element by the amount X which is the length of the overlap.

However, unlike the previous embodiments, surfaces 30B are all horizontal, each however displaced out of the plane of the corresponding surface 30B of at least one adjacent test element. Also, the reputation of the step pattern is different, as follows: numbering the support positions as A-G, left to right, Fig. 8, it is apparent that the supports at positions A and B are co-planar, but not co-planar with their outside adjacent positions G and C, respectively. For example, position C adjacent to position B is one-step down. Position D is in turn one-step down from C, and position E is one-step down, indeed the bottom-most step, from D. Positions F, G, and then A rise by a step from the previous ones, with step B being co-planar with position A again. The cycle thus repeats itself.

As in the previous embodiments, a ramp 180B is provided, to alter the orientation of a test element coming from dispensing station 16B, Fig. 8, to a different orientation at most of the support surfaces 30B. The reorientation is limited, however, to changing only the height of the test element, and the height need not be changed for one of surfaces 30B, e.g., the one at position E, if that position remains at the same height as support 174B at dispensing station 16B.

Unlike previous embodiments, ramp 180B is not a fixed surface, but rather a surface horizontally hinged at 300 at end 302 of the ramp, with opposite end 304 being raised & lowered, arrow 306, by a drive system, not shown, as needed to raise element E to the height of the intended incubator support surface 30B.

Alternatively, not shown, the means by which a test element is reoriented to mount it in the incubator can be an elevator mechanism such as that shown in U.S. Patent No. 5,419,871 by Muszak et al., instead of ramp 180B.

Cover 40B, Fig. 9, for incubator 20B is similar to cover 40A - it is a single fixed cover for the entire incubator, with a surface facing surfaces 30B, 32B that is complimentary to surfaces 30B, 32B. Thus, surfaces 230B have leaf springs 233B that cover the evaporative area of, and bias downwardly, the test element, whereas surfaces 232B allow for the overlap distance X plus a spacing for leaf spring 240B that biases each test element up against reference datum surface 32B. There is one exception -

past the metering station. Thus, slide supply station 12C is constructed exactly as the case of the embodiment of Fig. 5, to eject via blade 141C a slide test element E from either ring 132C out opening 164C to support 174C at metering station 16C. However, adjacent to metering station 16C is a fast shuttle 350 that traverses most of the distance to incubator 20C that rotates out of the horizontal, arrow 71C, so that support surfaces 30C are horizontal. The solid line surface 30C is at position 310 shown in Fig. 10. A low speed shuttle 352 receives elements E' from fast shuttle 350, all as described in Research Disclosure, Publication No. 34317, published in November of 1992, page 819. Shuttle 352 then transfers element E', arrow 356, to a surface 30C of incubator 20C.

the biasing spring at position D is not on cover 40B but is on one of the side surfaces of plate 34G at position D opposite to other side surface, which becomes reference datum surface 32B.

Because support surfaces 30B are at varying heights, the best method for scanning elements E after incubation is to remove them from the incubator, using a ramp similar to ramp 180B, to allow detection off-line by a photodetector providing a fixed Z-axis spacing each time. Examples of such off-line detection are shown in, e.g., U.S. Patent No. 5,034,191.

As with all previous embodiments, the incubator of Figs. 8 & 9 can alternatively be mounted for lineal reciprocation instead of for rotation, in which case plate 34B is linear, not curved.

In the embodiment of Figs. 8 and 9, the horizontal orientation of support surfaces 30B is achieved while rotating those surfaces parallel to the plane of rotation of the bottom surface 41B of plate 34B, shown as arrows 71B. However, this need not be the case. An alternative is to use the incubator 20 of Fig. 3, but with surface 41 inclined to the horizontal, shown as phantom horizon 300, by the same angle beta as is the incline of surfaces 30 from surface 41. This is further shown in Figs. 10 and 11, wherein parts similar to those previously described bear the same reference numeral to which the distinguishing suffix "C" is appended.

The rotation of the incubator about a plane tilted to the horizontal causes plate 34C, Fig. 10, to be canted, but surfaces 30C remain horizontal, allowing test element loading and unloading all at level 310, for example, eliminating the need for a ramp or elevator. Also, it allows the use of read apertures 70C, Fig. 11, for an on-analyzer scan, when the apertures pass read scan beam 312, since level 310 is fixed in space while incubator 20C rotates at its canted angle.

This embodiment also illustrates a different structure for the biasing of covers 42C downward and towards reference datum surface 32C. That is, Fig. 10, a plunger 314 is mounted within a sleeve 316 that is loosely fitted, Fig. 11, within housing 318 attached to the rotor. Upper portion 320 of sleeve 316 has a boss 322 chambered at 324 sufficient to allow it to articulate slightly within a depression 326 in housing 318. Lower end 328 of sleeve 316 snugly accommodates a shoulder 330 around lower portion 332 of plunger 314, which shoulder supports one end 334 of a compression spring 336 that is biased at its other end against upper sleeve portion 320. Lower portion 332 of the plunger terminates in a ball 338 that pivots within a ring 340 integral with cover 42C. The effect is to urge plunger 314 and cover 42C downward and to the left, arrows 342 and 344, relative to slide test element E on surface 30C.

Although the ramp or elevator is thus eliminated using a rotational plane canted out of the horizontal, it may be advantageous to hand-off metered test elements E', Fig. 12, to a second transfer system, thus avoiding extending the pusher blade

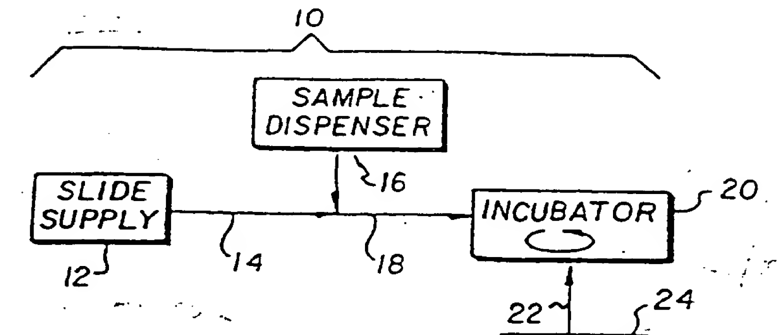


FIG. 1

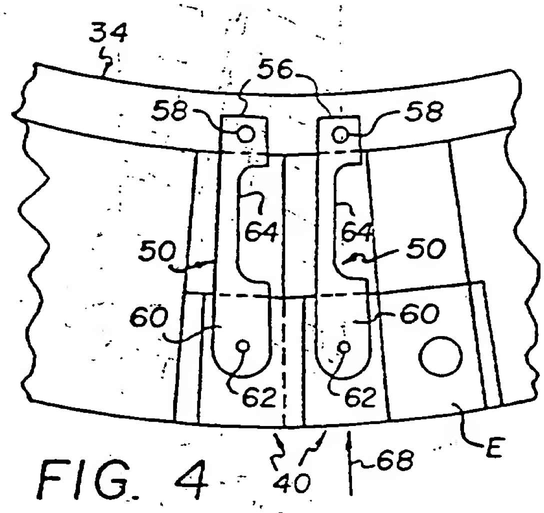


FIG. 4

FIG. 6

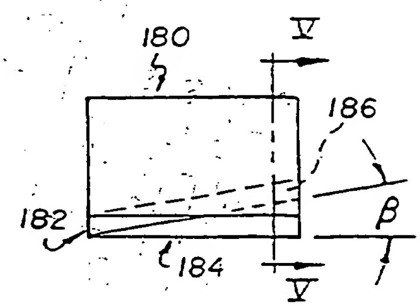
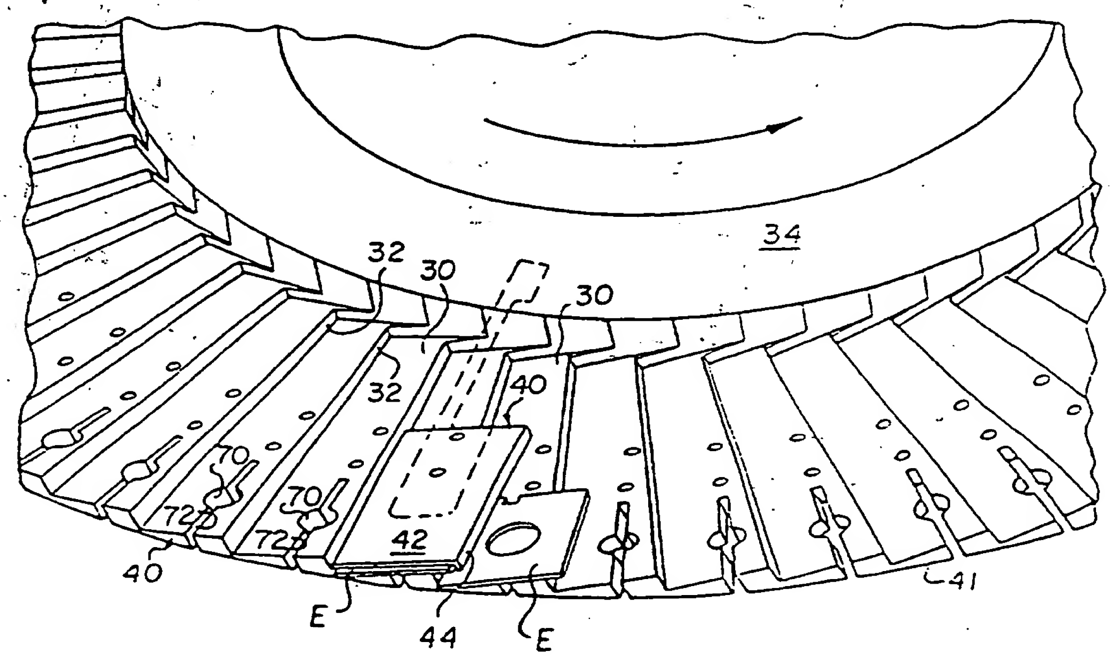


FIG. 2



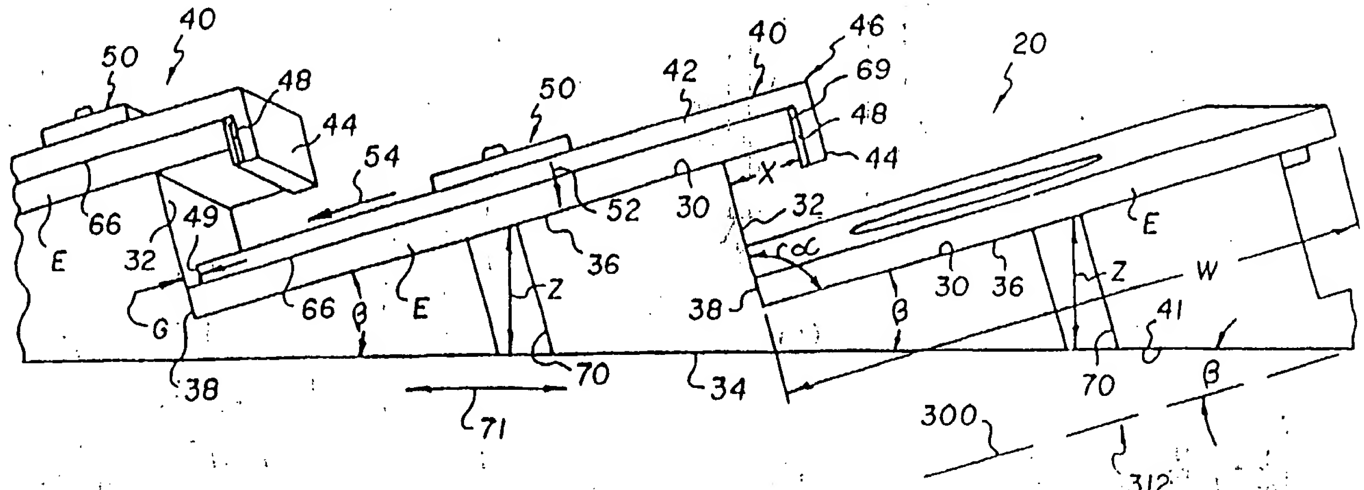

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FIG. 3

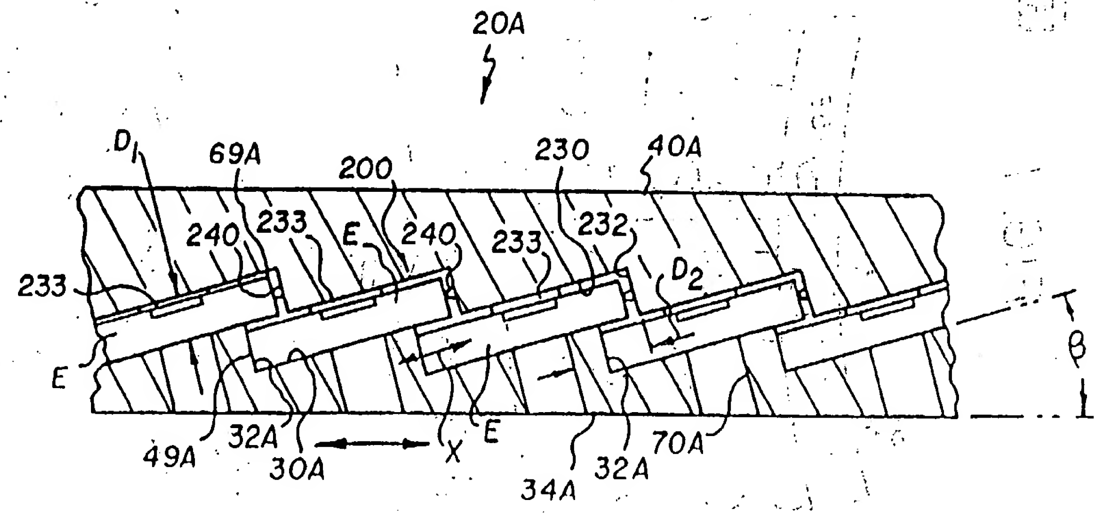
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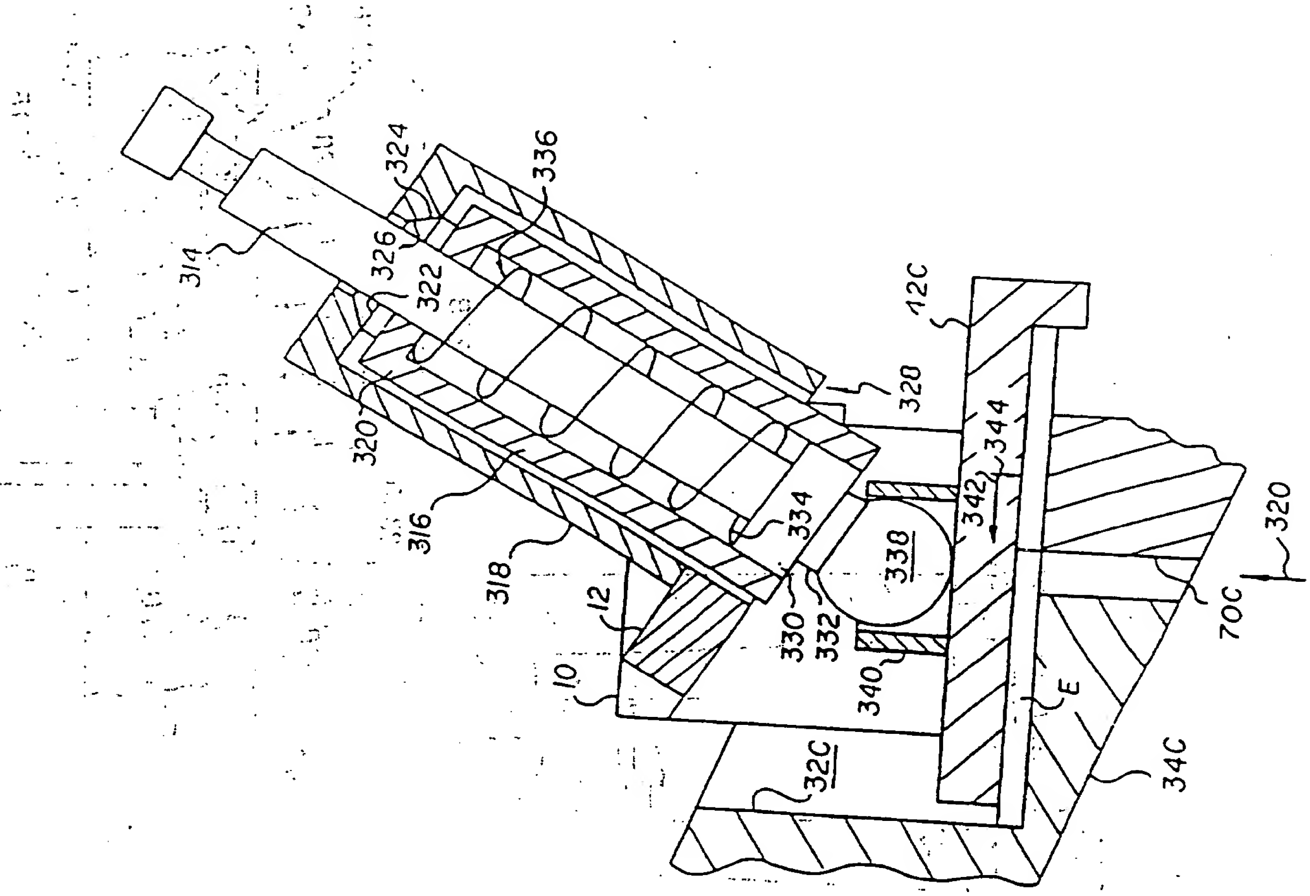
FIG. 7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32C

FIG. 11

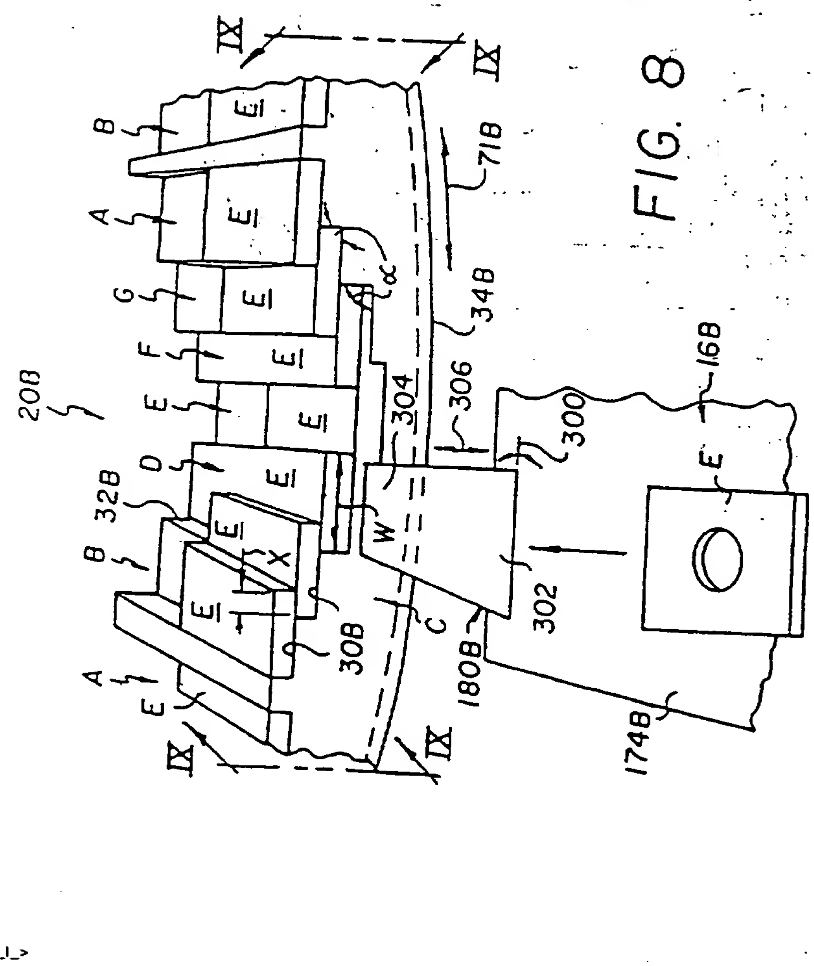
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FIG. 8

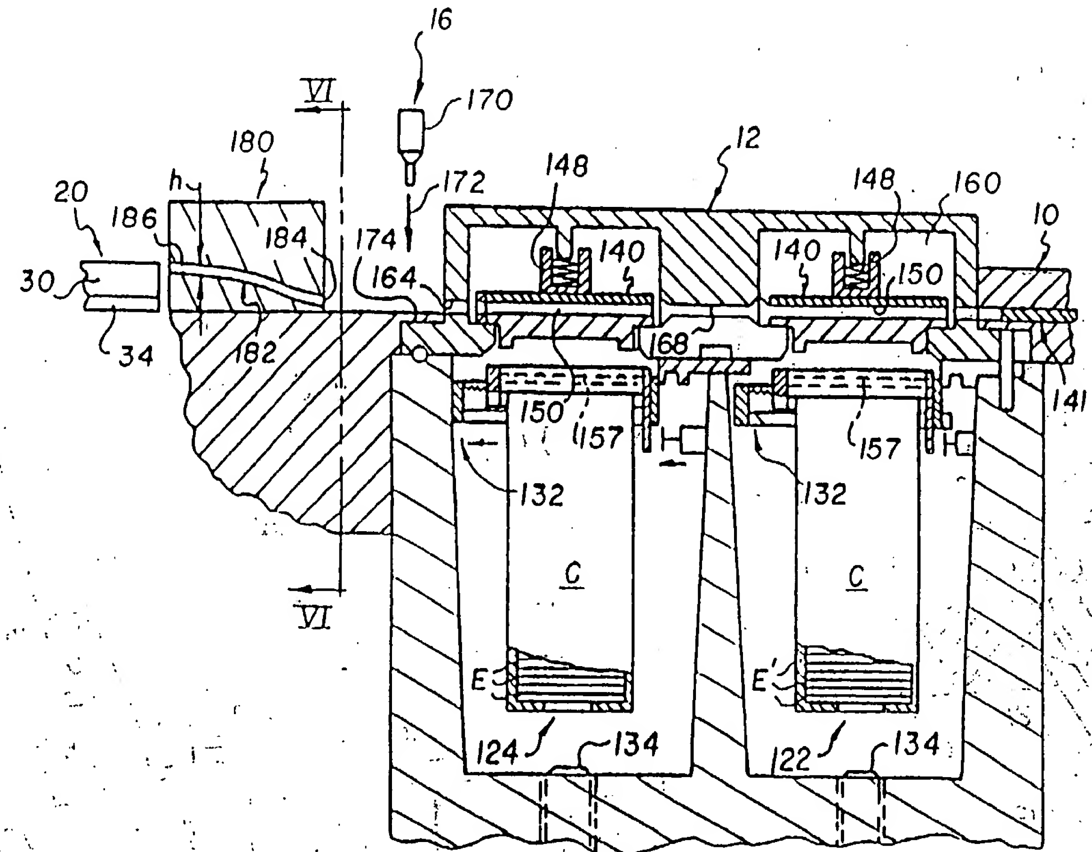
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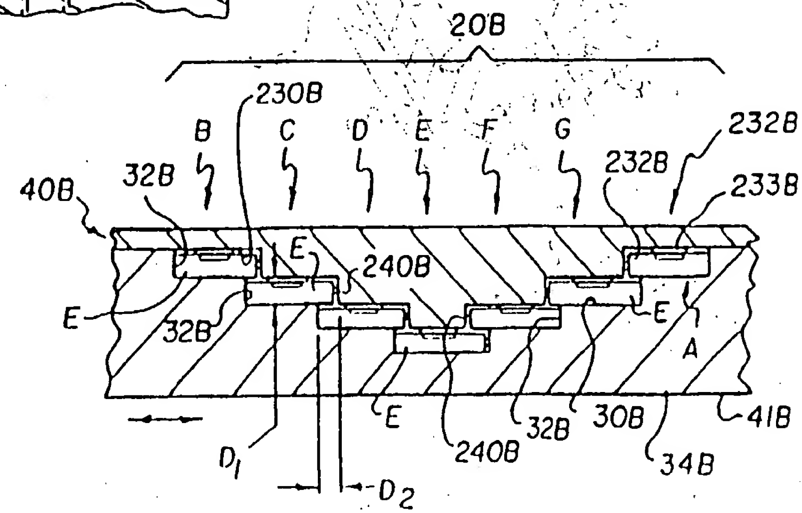
FIG. 5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34B
D2

FIG. 9

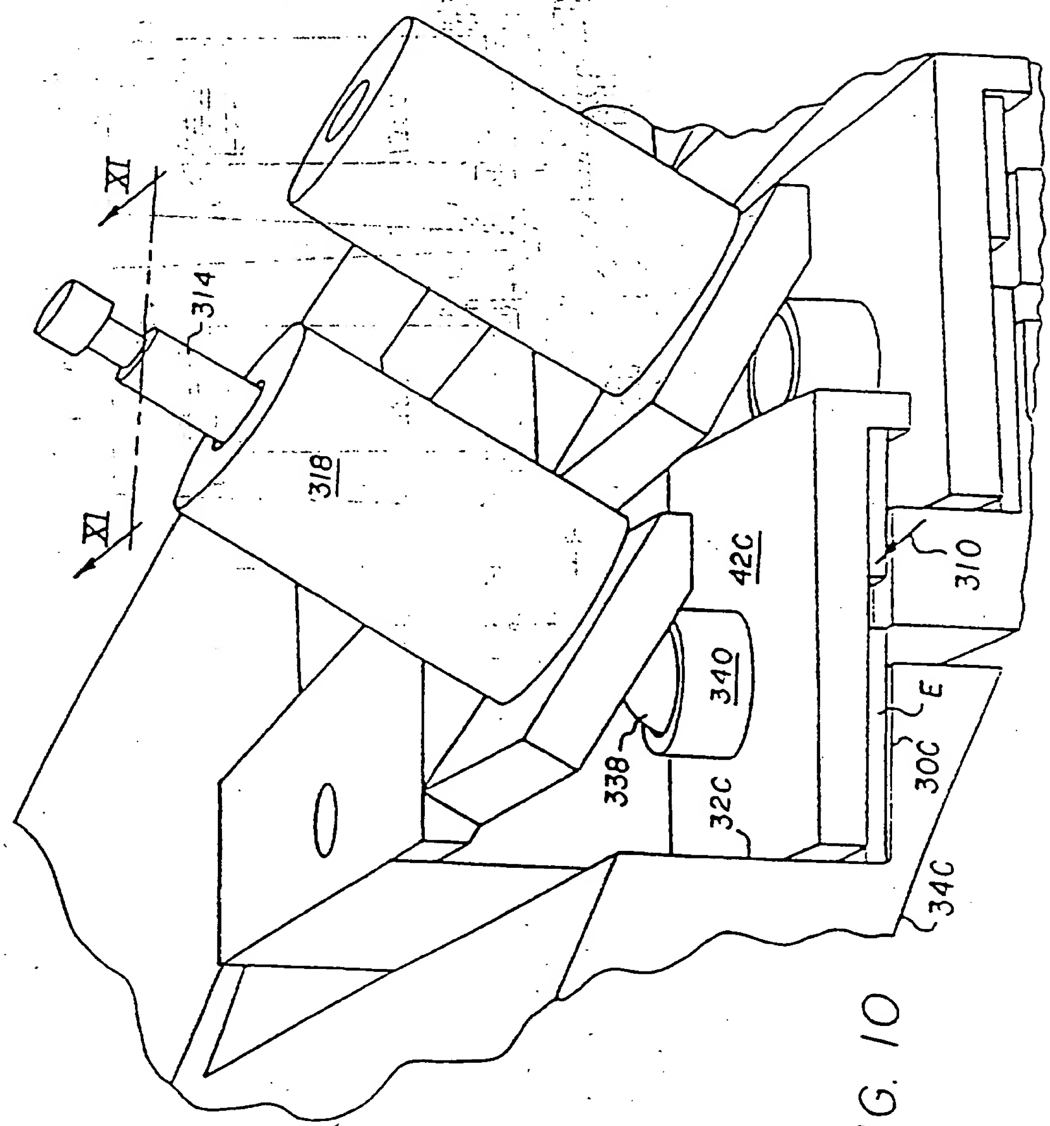

FIG. 10

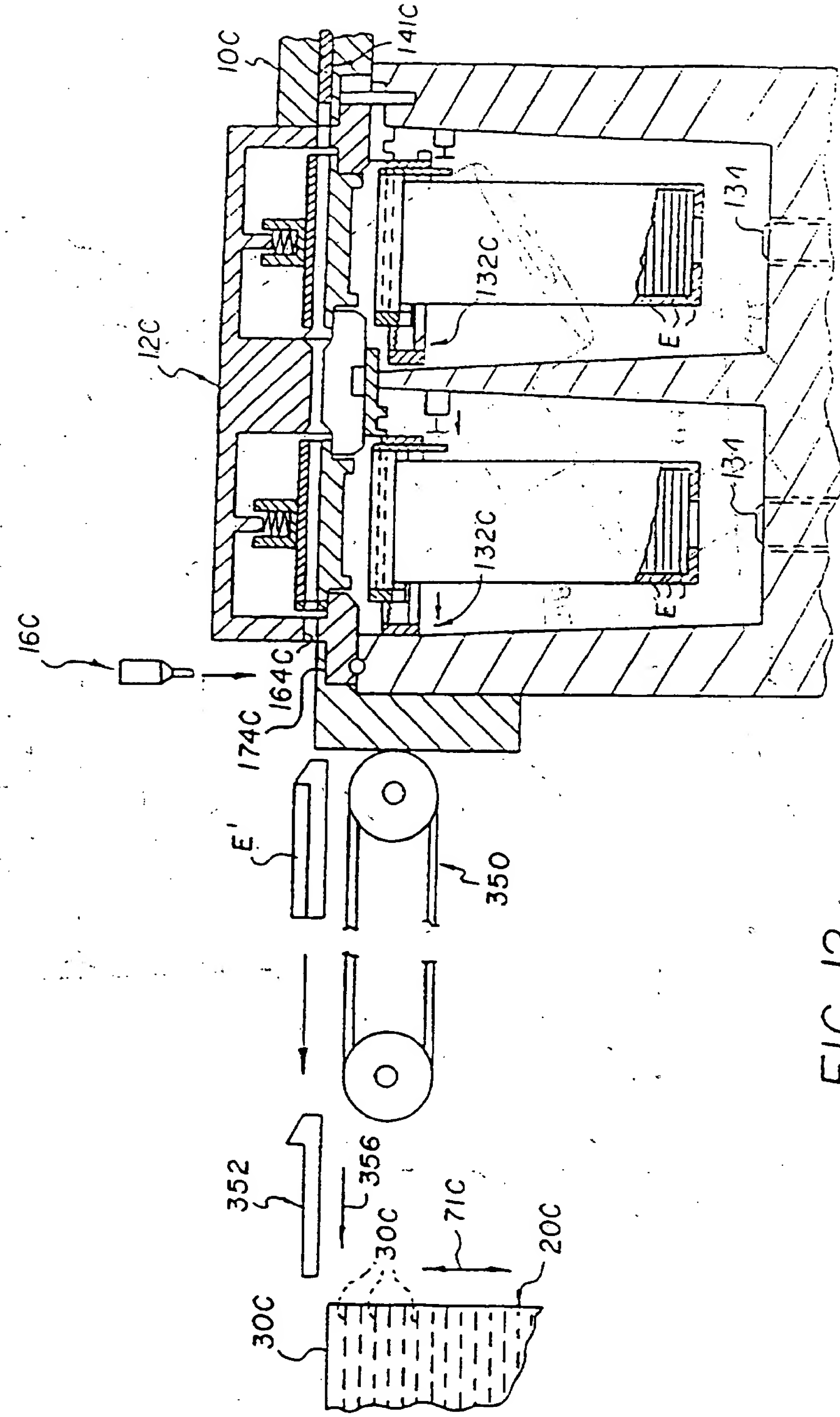

FIG. 12

Disclosed anonymously
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